

**REMARKS/ARGUMENTS**

Claims 1 and 19-36 are pending. Claims 2-18 were previously canceled. All pending claims stand substantively rejected. In this Amendment, claim 22 is canceled, and claims 1, 23-25, and 34-36 are amended. Reconsideration of the claims is respectfully requested. The paragraph numbering below follows that of the Detailed Action.

**Claim Amendments**

Claims 1 and 34-36 are amended to incorporate elements from canceled claim 22. Further support for amended claim 34 is found in the specification at, for example, page 8, lines 7-17. Claims 23-25 are amended to conform dependencies. No new matter is introduced.

**Double Patenting**

¶1. Claims 1, 19-25, 28, 29, and 31-34 were rejected as allegedly unpatentable over claims 1-31 of commonly owned U.S. Patent No. 6,063,061 to Wallace et al. ["Wallace '061"], on the ground of nonstatutory obviousness-type double patenting. This rejection is overcome by submission of the accompanying Terminal Disclaimer. Withdrawal of this rejection is respectfully requested.

**First Rejection Under 35 U.S.C. §102**

¶2. Claims 1, 19-24, 28, 29, and 34 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 6,110,484 to Sierra et al. ["Sierra"]. This rejection is traversed. According to MPEP 2131, to anticipate a claim, a cited reference must teach every element of the claim. Sierra fails to meet this test.

Presently pending independent claims 1 and 34 are drawn to a fragmented single phase aqueous colloid.

**Sierra Describes a Dried Powder, Not a Fragmented Aqueous Colloid**

In contrast to the presently claimed fragmented aqueous colloid, Sierra describes a freeze-dried powder. At col. 8, lines 3-8, Sierra describes forming a gelatin-SPEG gel. The gel is then lyophilized and pulverized. Lyophilization, which is also known as freeze-drying, typically involves freezing a material and reducing the surrounding pressure to allow the frozen

water in the material to sublime from the solid phase to gas. It is a drying process whereby the water is removed. A gel which has been lyophilized is dried and contains no water, and thus is not the same as the presently claimed aqueous colloid.

Example 3 of Sierra also describes reconstituting a lyophilate with a Tris buffered saline to form a resultant slurry. However, there is no teaching or suggestion that this resultant slurry includes a fragmented single phase aqueous colloid as presently claimed. Further, there is no teaching or suggestion that the resultant slurry when fully hydrated in the range from 0.01 mm to 5 mm, nor that the resultant slurry has an equilibrium swell from 400% to 5000%, nor that the resultant slurry has an in vivo degradation time of less than one year.

It is improper to conclude that a degradation time of less than one year is inherent to Sierra's pulverized gelatin. Sierra's gelatin is **not** prepared according to the same procedure provided in the instant application, as shown by the following table. Thus, there is no basis for this inherency rejection.

<b>Example 3 (Instant Application)</b>	<b>Example 3 (Sierra)</b>
Gelatin allowed to swell in distilled water at 1-10% solids (w/w) chilled to 5°C.	Phosphate-buffered saline added to dilute gelatin to a concentration of 15 mg/mL.
Resultant hydrogel fragmented by stirring with an impeller driven by a motor.	SPEG added to gelatin solution for a final concentration of 10 mg/mL.
NaIO <sub>4</sub> and NaOH added to achieve 0.05M NaIO <sub>4</sub> and 0.10M NaOH. Held at 0°-8°C for 2-3 days.	Gelatin-SPEG solution allowed to cool to room temperature and gel.
Fragments washed with 5°C water to achieve pH 8.	Gel lyophilized and pulverized by grinding mill.
Fragments washed with aqueous buffer and left at 0°-8°C to equilibrate with buffer.	
Free buffer decanted.	

Moreover, the requirements for a rejection based on inherency are well established, and any rejection under inherency must follow these guidelines. As set out in MPEP 2112, in procedural terms the initial burden is on the Examiner to provide rationale or evidence tending to show inherency. MPEP 2112 (IV) provides the following guidance regarding inherency.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it

would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' ”; and

““In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”

It has not been shown that the presently claimed degradation time *must* flow as a natural consequence from the technological constraints of Sierra, and thus the conclusion of the inherency rejection is improper.

Based on the above, Sierra fails to teach or suggest each of the elements of presently pending independent claims 1 and 34, and therefore does not anticipate these claims. Claims 22-24, 28, and 29 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the novel combination of elements they recite. Claims 19-21 are canceled. Withdrawal of this rejection is respectfully requested.

#### First Rejection Under 35 U.S.C. §103

¶3. Claims 25-29 were rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 6,110,484 to Sierra et al. [“Sierra”]. . This rejection is traversed.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited reference must teach or suggest all the claim elements. As noted above, Sierra fails to teach or suggest each and every element of presently pending independent claim 1. Claims 25-29 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. Withdrawal of this rejection is respectfully requested.

#### Subsequent Rejections

The rejections from the Office Action dated May 27, 2005 were maintained in the most recent Office Action. To avoid prolixity, rather than reiterating the reasons for patentability as set forth in the previously filed Amendment, Applicant instead addresses the “Response to Arguments” as set forth in the most recent Office Action at pages 6-8.

Second Rejection Under 35 U.S.C. §102

¶4. Claims 1, 20-23, 25, 30, and 35 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,818,517 to Kwee et al. ["Kwee"]. This rejection is traversed.

The Office Action alleges that Kwee does not describe a hydrogel having two phases. Applicants submit that claim 1 of Kwee in fact describes such a hydrogel, more specifically a two phase hydrogel having (1) a first phase including a water-insoluble polymer, and (2) a second phase including a water-soluble thickening agent. Because the polymer is *water-insoluble*, and is in the presence of a *water-soluble* thickening agent, there clearly are two different phases in Kwee's composition.

Kwee reports that the water-insoluble polymer is swellable in water, yet there is no teaching or suggestion that the water-insoluble polymer, when swelled with water, would exist in a single phase (aqueous or otherwise) along with the water-soluble thickening agent. Conversely, Kwee reports that the water-soluble thickener increases the viscosity of an amount of water in which it is dissolved, yet there is no teach or suggestion that the water-soluble thickener, when dissolved in the water, would exist in a single phase (aqueous or otherwise) along with the water-insoluble polymer. Thus, neither of Kwee's two different phases, either alone or in combination with one another, anticipate the presently claimed single phase aqueous colloid which is substantially free from a free aqueous phase.

Based on the above, Kwee fails to teach or suggest each of the elements of independent claims 1 and 35, and therefore does not anticipate these claims. Claims 22-23, 25, and 30 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the novel combination of elements they recite. Claims 20-21 are canceled. Withdrawal of this rejection is respectfully requested.

First Rejection Under 35 U.S.C. §103

¶5. Claims 19, 24, 31, 32, and 36 were rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 4,818,517 to Kwee et al. ["Kwee"]. Applicants traverse this rejection.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited reference must teach or suggest all the claim elements. As noted above, Kwee fails to teach or suggest each and every element of amended independent claim 1, and for many of the same reasons, Applicants submit that Kwee fails to teach or suggest each and every element of presently pending independent claim 36, which recites a single phase aqueous colloid that is substantially free from a free aqueous phase.

Claims 24, 31, and 32 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. Claim 19 is canceled. Withdrawal of this rejection is respectfully requested.

Second Rejection Under 35 U.S.C. §103

¶5. Claims 26-29, 33, and 34 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 4,818,517 to Kwee et al. in view of U.S. Patent No. 4,837,285 to Berg et al. ["Berg"]. Applicants traverse this rejection.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited references when combined must teach or suggest all the claim elements.

As noted above, Kwee fails to teach or suggest each and every element of amended independent claim 1, and for many of the same reasons, Applicants submit that Kwee fails to teach or suggest each and every element of amended independent claim 34, which recites a single phase aqueous colloid which is substantially free from a free aqueous phase. Berg fails to remedy the deficiencies of Kwee, because Berg fails to teach or disclose a single phase aqueous colloid which is substantially free from a free aqueous phase as presently claimed.

Claims 26-29 and 33 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. Withdrawal of this rejection is respectfully requested.

Appl. No. 09/553,969

Amdt. dated

Reply to Office Action of November 17, 2005

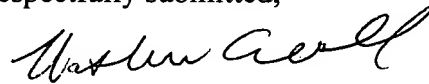
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**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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